

REMARKS

Claims 1, 2, 4-19, and 27-49 are pending in the present application. The Examiner has withdrawn claims 27-43 and 46-49 from consideration as being drawn to non-elected subject matter. Claims 1, 2, 4-19, and 44-45 remain pending and under examination.

The March 27, 2007 Final Office Action

Examiner's rejections under 35 U.S.C. §103

The Examiner maintained the previous rejection of all pending claims as allegedly obvious over Gorbach, et al. (U.S. Pat. No. 6,060,070) alone, or Gorbach in combination with Miller (U.S. Pat. No. 6,159,959).

Applicants first note that the Examiner has rejected claims 1-2, 4-5, 12-17, 19, 44, and 45 as obvious over Gorbach alone. The Examiner's position is essentially that Gorbach refers to "equol", that one of ordinary skill in the art would simply presume that this reference is to racemic equol, and that it is within the ability of one of ordinary skill in the art to resolve the racemate into its individual enantiomers. Based on these assumptions, the Examiner has concluded that Applicants' claims, which recite compositions consisting essentially of the S enantiomer of equol (S-equol), are obvious. The Examiner suggests that a showing of unexpected results over the teachings of the cited art would be required to overcome the obviousness rejection.

In response, Applicants respectfully traverse the Examiner's rejection. Applicants'

invention is directed to, *inter alia*, a composition for use in making commercial products, consisting essentially of the S enantiomer of equol (S-equol). The Examiner has not cited any art that makes any mention of enantiomers of equol and certainly no art that would teach or suggest compositions consisting essentially of the S-enantiomer of equol. Rather, the Examiner's position relies entirely on an initial assumption that Gorbach teaches a racemate of equol. Gorbach, however, refers simply to "equol," as one of a long list of isoflavonoids. Indeed, it is unclear from Gorbach what in fact is even being referred to. Applicants note the following disclosure, found at column 1 of Gorbach (and consistent with other disclosures throughout the patent):

Purified isoflavonoids which may be administered according to the invention include genistein, daidzein, biochanin A, formononetin, O-desmethylangolensin, glycitin, and equol; these may be administered alone or in combination.

Accordingly, the invention provides a method of treating or preventing, in a person, one or more symptoms of aging skin, e.g., wrinkles, by applying to the person's skin a composition containing a dermatologically acceptable base containing between 1 and 40 mg purified isoflavonoid per gram of base; the isoflavonoid is one of the naturally-occurring isoflavonoids listed above.

By "purified" is meant the isoflavonoid is in a form which is more concentrated than the form in which it occurs naturally in plants.

Notwithstanding the inclusion of equol among the above-listed isoflavonoids, no naturally-occurring plant derived source of equol is known. Moreover, even if the substance referred to as "equol" in Gorbach were so derived, there would be no reason to believe it was a

racemate, as Applicants are unaware of any naturally occurring substance that is derived from nature as a racemate. As such, Gorbach makes no mention whatsoever of racemic equol. Moreover, and more significantly, Gorbach makes no mention of the structure or chirality of equol (or any other compound referred to therein). Accordingly, Gorbach simply does not by itself support either the Examiner's rationale or her conclusion of obviousness, because the cited reference simply does not contain the disclosure upon which the Examiner's position relies. In that regard, Applicants note the following, of which the Examiner is undoubtedly aware:

As stated in MPEP §2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added.)

See also MPEP §2143.01, which further notes that in *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004), the court emphasized that the proper inquiry is "whether there is something in the prior art as a whole to suggest the *desirability*, and thus, the obviousness, of making the combination."

In a case such as this one, therefore, there must be a suggestion from the prior art that a particular racemate can be resolved into its separate enantiomers by a particular technique with a reasonable expectation of success, and that there is some desire to do so. The art cited by the Examiner falls well short of such teachings and thus, the Examiner has failed to make out a *prima facie* case of obviousness. To reiterate, nothing in the art relied on by the Examiner suggests any structure of equol, its possible chirality, or that it does or does not exist as a racemate. Consequently, the art relied on by the Examiner cannot suggest that it would be desirable to obtain individual enantiomers of equol, and cannot suggest methods that could be used to achieve the isolation of such enantiomers with any expectation of success. Finally, of course, nothing in the art relied on by the Examiner suggests a composition consisting essentially of S-equol. For these reasons, the Examiner's present obviousness rejection cannot be maintained and therefore should be withdrawn.

With respect to the Examiner's suggestion that unexpected results are required to establish nonobviousness of the present claims, Applicants respectfully direct the Examiner's attention to the following, as stated in MPEP §2142:

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness . . . The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to suggest the claimed invention.

Accordingly, because the Examiner has not set forth a *prima facie* case of obviousness, Applicants are under no obligation to submit any evidence of nonobviousness at this time.

Applicants note that the Examiner also has rejected claims 18, 44, and 45 as allegedly obvious over Gorbach in view of Miller. Each of these claims similarly refers to compositions *consisting essentially* of S-equol. As Applicants have previously noted, Miller does not teach or suggest C-4' or C-7 conjugates of equol. More importantly, Miller supplies none of the teachings missing from Gorbach which would be required to sustain a proper obviousness rejection of the present claims. Accordingly, the rejection of claims 18, 44, and 45 is improper for the reasons set forth above in connection with the failings of the Gorbach reference. None of the present claims are rendered obvious over any combination of Gorbach and Miller. Therefore, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. §103.

Applicants' Comments on a Previously Submitted Reference

Applicants wish to make the following comments of record concerning a reference, U.S. Pat. No. 6,716,424 (Uchiyama, et al.), that was previously submitted and considered by the Examiner in connection with this application. (See IDS submitted September 15, 2004 and considered by Examiner Chung October 5, 2006).

Uchiyama refers to, among other things, methods of producing "equol" utilizing various strains of microorganisms. Like Gorbach, Uchiyama makes no explicit mention of a racemate or of the structure or chirality of equol. Rather, Uchiyama makes a reference to a very simplistic

process which purportedly results in a product called “crude equol” obtained from a fermentation broth. (See col. 11, lines 31-42). It is not clear from the reference what this “crude equol” might be or what it might or might not contain, and the description of the process by which it is purportedly obtained is too vague and simplistic to offer one of ordinary skill in the art any guidance as to its composition. It is clear, however, that the Uchiyama reference does not explicitly refer to any compositions consisting essentially of S-equol, and thus, it does not explicitly teach or suggest the Applicants’ claims.

Applicants do wish to direct the Examiner’s attention to Applicants’ specification, beginning at page 17, which notes that it is now known (but was not at the time of Uchiyama) that under optimum conditions, and using particular starting materials and process steps, S-equol can be obtained through bacterial conversion of daidzein or a related isoflavone. As noted above, while it is not clear what Uchiyama’s “crude equol” might be, and thus what compositions comprising it might variously contain, it is clear to Applicants that the vague process steps discussed in Uchiyama would not necessarily result in compositions consisting essentially of S-equol, as required by Applicants’ present claims, and thus does not teach or suggest the Applicants’ claims, either explicitly or inherently.

Applicants note this because, as the Examiner is aware, for a prior art teaching to inherently anticipate a claim limitation, the allegedly inherent characteristic must *necessarily* flow from the teachings of the prior art reference. The fact that a certain result or characteristic *may* be present in the prior art is not sufficient to establish the inherency of that result or

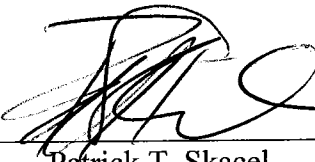
characteristic. Here, of course, whatever the compositions of Uchiyama may or may not contain, a composition consisting essentially of S-equol clearly would not *necessarily* flow from the vague teachings of Uchiyama that result in what is referred to therein as "crude equol." Accordingly, Uchiyama does not impact the patentability of Applicants' present claims.

In view of the above remarks, Applicants believe all of the Examiner's concerns set forth in the March 27, 2007 Office Action have been overcome and the claims are in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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